

The Clinical Evaluation of NovaBone for the Treatment of Tibial Fractures

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Jiangsu Med., Feb2004, Vol 30, No.2, p84-87

Introduction:

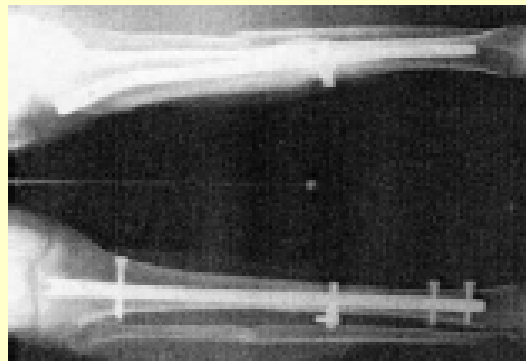
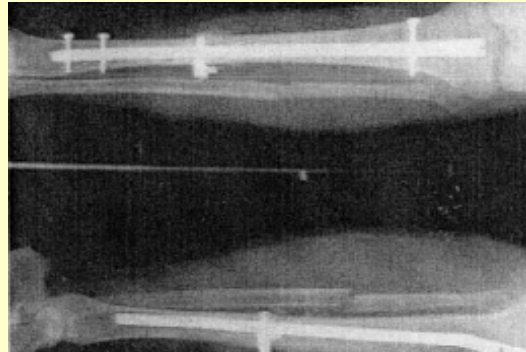
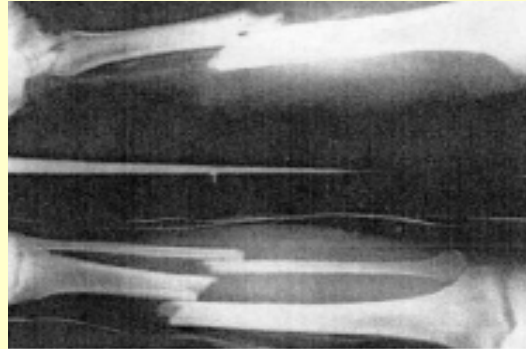
Tibial fractures are known to have long healing times and high rates of bone nonunion. Therefore the authors set out to expedite the healing rate of bone fractures and lower the rate of bone nonunion. In this study the authors elected to use NovaBone Particulate to accelerate the healing process and repair damaged bone.

Methods:

NovaBone was used in the experimental group in conjunction with open reduction and internal fixation of tibial fractures from March 2002-January 2003. A total of 78 patients were treated for fresh fracture of the tibia injuries, 47 Male Cases, 31 Female Cases, Ages 17-78 years old, Average Age 40.5 years old. Patients were randomly divided, 40 cases into an experimental group (fractured part of the bone was treated with NovaBone) and 38 cases into a control group (did not receive NovaBone)

Surgical Indications:

One third of the middle, top, and bottom borders of closed fractures or I°-II° open fractures used interlocking nail fixation, while fractures near the knee or ankle used steel plate fixation



Results:

All patients received between 5-8 months of follow up visits, averaging 6 months. The experimental group's clinical and bone healing time was 9-10 weeks and 11-12 weeks respectively. Clinical and bone healing times of the control group were 13.5-14.5 weeks and 15.5-16.5 weeks respectively. The healing time of the control group were all later than the experimental group by 4-5 weeks.

Table of Results

	Week 8	Week 12	Week 16
Exp. Group			
40 cases	12 Excellent 28 Good	35 Excellent 5 Good	40 Excellent
Control Group			
38 cases	6 Good 20 Okay 12 Poor	2 Excellent 25 Good 10 Okay 1 Poor	37 Excellent 1 Okay

Discussion:

Tibial fractures are very common and with surgical procedures including nails, pressurization, or steel plate internal fixation, etc. However common disadvantages of all of the above methods are that they take a long time for fractures to heal. Reports in the literature show non-union rates as high as 20%-40% This experimental group was treated with NovaBone on the fracture line or defect site after internal fixation. As a result, clinical and bone healing times were all 4-5 weeks shorter than the control group

NovaBone showed a clinical ability to expedite bone healing and should routinely be used in the clinical setting.